



200.1133CONS  
*IFW*

**UNITED STATES PATENT AND TRADEMARK OFFICE**

Re: Application of: Benjamin OSHLACK, et al.  
Serial No.: 10/700,906  
Examiner: To be Assigned  
Art Unit: 1615  
Filed: November 4, 2003  
For: **TAMPER-RESISTANT ORAL OPIOID  
AGONIST FORMULATIONS**

**PETITION TO ESTABLISH PRIOR RECEIPT IN THE U.S.P.T.O. OF ITEM(S)  
CONSIDERED AS OMITTED**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

October 4, 2004

Sir:

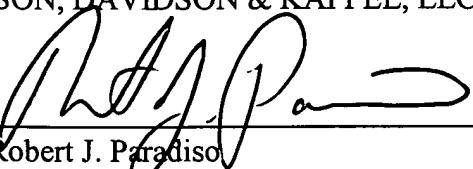
Applicant petitions the Commissioner for Patents that the omitted item(s), page 50 of the specification, as noted in the Notice Of Omitted Items, dated September 28, 2004, a copy of which is enclosed, was in fact deposited in the U.S. Patent and Trademark Office with the nonprovisional papers on November 4, 2003. Applicant has enclosed a copy of the submitted item, page 50, which was included in the 86 page specification, claims, and abstract portion of the application, and a copy of the return postcard reflecting the receipt of the 86 pages, as evidence of such deposit.

A check for \$130.00 is enclosed which covers the petition fee in accordance with 37 C.F.R 1.17(h).

Applicant respectfully requests that, upon grant of the petition under 37 C.F.R. 1.182, the petition fee be refunded, and the Commissioner is hereby authorized to credit the refund to Deposit Account No. 50-0552.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 

Robert J. Paradiso

Reg. No. 41,240

Davidson, Davidson & Kappel, LLC  
485 Seventh Avenue, 14<sup>th</sup> Floor  
New York, N.Y. 10018  
(212) 736-1940

FORM PTO -1083  
BOX: Missing Parts  
COMMISSIONER FOR PATENTS  
Alexandria, VA 22313-1450



Docket No.: 200.1133CON5  
Date: October 4, 2004

In re application of: Benjamin OSHLACK et al.  
Serial No.: 10/700,906  
Filed: November 4, 2003  
For: TAMPER-RESISTANT ORAL OPIOID AGONIST FORMULATIONS  
S i r:

Transmitted herewith is a Petition to Establish Prior Receipt of Omitted Items in the above-identified application.

Small entity status under 37 C.F.R. 1.9 and 1.27 has been previously established.  
 Applicants assert small entity status under 37 C.F.R. 1.9 and 1.27.  
 No fee for additional claims is required.  
 A filing fee for additional claims calculated as shown below, is required:

(Col. 1) FOR :	(Col. 2)		SMALL ENTITY		OR	LARGE ENTITY	
	REMAINING AFTER	HIGHEST PREVIOUSLY PRESENT	RATE	Fee		RATE	Fee
	AMENDMENT	PAID FOR		EXTRA			
TOTAL CLAIMS	*	Minus** 20=		x \$ 9 \$		x \$ 18 \$	
INDEP. CLAIMS	*	Minus*** 3 =		x \$ \$		x \$ 84 \$	
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEP. CLAIM			+ \$	\$		+ \$280 \$	
					TOTAL: \$	OR	TOTAL: \$

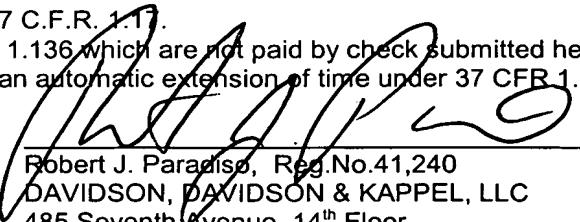
\* If the entry in Co. 1 is less than the entry in Col. 2, write "0" in Col. 3.  
\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.  
\*\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

Also transmitted herewith are:  
 Petition for extension under 37 C.F.R. 1.136 (2 pages)  
 Other: Copy of Notice of Omitted Items (2 pages)  
    Page 50 of the Specification (1 page)  
    Copy of the returned postcard (1 page)

Check(s) in the amount of \$ 130 .00 is/are attached to cover:  
 Basic filing fee  
 Petition fee under 37 C.F.R. 1.136  
 Other:

The Assistant Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.

Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.  
 Any patent application processing fees under 37 C.F.R. 1.17.  
 Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

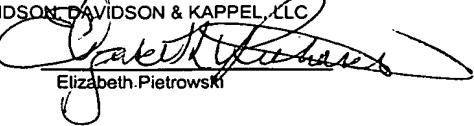


Robert J. Paradise, Reg. No. 41,240  
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I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with the United States Postal Service with sufficient postage as "first class mail" in an envelope addressed to Mail Stop: Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on October 4, 2004.

DAVIDSON, DAVIDSON & KAPPEL, LLC

BY:



Elizabeth Pietrowski

## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
10/700,906	11/04/2003	Benjamin Oshlack	200.1133CONS

DAVIDSON, DAVIDSON & KAPPEL, LLC  
 14th Floor  
 485 Seventh Avenue  
 New York, NY 10018

CONFIRMATION NO. 1129  
**FORMALITIES LETTER**



\*OC000000013919309\*

Date Mailed: 09/28/2004

**NOTICE OF OMITTED ITEM(S) IN A NONPROVISIONAL APPLICATION**

**FILED UNDER 37 CFR 1.53(b)**

A filing date has been accorded to the above-identified nonprovisional application papers; however, the following item(s) appear to have been omitted from the application:

- Page(s) **50** of the specification (description and claims).

I. Should applicant contend that the above-noted omitted item(s) was in fact deposited in the U.S. Patent and Trademark Office (USPTO) with the nonprovisional application papers, a copy of this Notice and a petition (and \$130.00 petition fee (37 CFR 1.17(h))) with evidence of such deposit **must** be filed within **TWO MONTHS** of the date of this Notice. The petition fee will be refunded if is determined that the item(s) was received by the USPTO.

II. Should applicant desire to supply the omitted item(s) and accept the date that such omitted item(s) was filed in the USPTO as the filing date of the above-identified application, a copy of this Notice, the omitted item(s) (with a supplemental oath or declaration in compliance with 37 CFR 1.63 and 1.64 referring to such items), and a petition under 37 CFR 1.182 (with the \$130.00 petition fee (37 CFR 1.17(h))) requesting the later filing date **must** be filed within **TWO MONTHS** of the date of this Notice.

Applicant is advised that generally the filing fee required for an application is the filing fee in effect on the filing date accorded the application and that payment of the requisite basic filing fee on a date later than the filing date of the application requires payment of a surcharge (37 CFR 1.16(e)). To avoid processing delays and payment of a surcharge, applicant should submit any balance due for the requisite filing fee based on the later filing date being requested when submitting the omitted items(s) and the petition (and petition fee) requesting the later filing date.

III. The failure to file a petition (and petition fee) under the above options (I) or (II) within **TWO MONTHS** of the date of this Notice (37 CFR 1.181(f)) will be treated as a constructive acceptance by the applicant of the application as deposited in the USPTO. **THIS TWO MONTH PERIOD IS NOT EXTENDABLE UNDER 37 CFR 1.136(a) OR (b).** In the absence of a timely filed petition in reply to this Notice, the application will maintain a filing date as of the date of deposit of the application papers in the USPTO, and original application papers (i.e., the original disclosure of the invention) will include only those application papers present in the USPTO on the date of deposit.

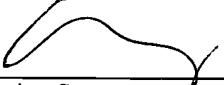
In the event that applicant elects not to take action pursuant to options (I) or (II) above (thereby constructively electing option (III)), amendment of the specification to renumber the pages consecutively and cancel incomplete sentences caused by any omitted page(s), and/or amendment of the specification to cancel all references to any omitted drawing(s), relabel the drawing figures to be numbered consecutively (if necessary), and correct the

references in the specification to the drawing figures to correspond with any relabeled drawing figures, is required. A copy of the drawing figures showing the proposed changes in red ink should accompany with any drawing changes . Such amendment and/or correction to the drawing figures, if necessary, should be by way of preliminary amendment submitted prior to the first Office action to avoid delays in the prosecution of the application.

Replies should be mailed to: Mail Stop Missing Parts  
Commissioner for Patents  
P.O. Box 1450  
Alexandria VA 22313-1450

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*A copy of this notice **MUST** be returned with the reply.*

  
Customer Service Center  
Initial Patent Examination Division (703) 308-1202  
PART 2 - COPY TO BE RETURNED WITH RESPONSE



Our Ref. 200.1133CONS November 4, 2003

RJP/HMS/

RE: Patent Application: Benjamin OSHLACK, et al.

Serial No.: To Be Assigned

Filed: Herewith

For **TAMPER-RESISTANT ORAL OPIOID  
AGONIST FORMULATIONS**

Enclosed:

- Continuation Utility Application Transmittal (4 pages);
- Specification (86 pages);
- Informal Drawings (3 pages);
- Copy of Executed Declaration and Power of Attorney (2 pages);
- Certificate of Express Mail (1 page);
- Preliminary Amendment (3 pages);
- Information Disclosure Statement Letter (4 pages);
- Form PTO-1449 (21 sheets);
- copies of commonly assigned pending specifications and claims -Exhibit A; and
- Check in the amount of \$770.00.

WITH EXPRESS MAIL LABEL NO. EV 319058938 US

MAIL STOP: PATENT APPLICATION  
RECEIVED BY:

17354 U.S.PTO  
10/700906  
  
110403

✓  




FORMULA:

Ingredients	Amt/unit (mg)
<b>LOADING</b>	
Naltrexone HCl	5.0
Sugar Spheres (30/35 mesh)	50.0
Opadry White Y-5-7068	2.5
Purified Water	42.5*
<b>OVERCOATING</b>	
Opadry White Y-5-7068	3.02
Purified Water	17.11*
<b>NON-RELEASE COATING (FOR RENDERING OPIOID ANTAGONIST SUBSTANTIALLY NON-RELEASABLE)</b>	
Eudragit RS30D (dry wt.)	12.10
Triethyl Citrate	2.42
Talc	4.84
Purified Water	49.21*
<b>OVERCOATING</b>	
Opadry White Y-5-7068	4.12
Purified Water	23.35*
Total	84.0

\* Remains in product as residual moisture only.

10    PROCESS:

1.    Solution Preparation      Dissolve the Naltrexone HCl in Purified Water. Once dissolved, add the Opadry White and continue mixing until a homogeneous dispersion is yielded.
2.    Loading      Apply the above dispersion onto the Sugar Spheres using a fluid bed coating machine.
- 15    3.    Overcoating      Prepare an overcoating solution by dispersing Opadry White in Purified Water. Apply this dispersion over the sugar spheres loaded with Naltrexone HCl using a fluid bed coating machine.
4.    Retardant Coating      Prepare the non-release coating solution by mixing the Eudragit RS30D, Triethyl Citrate, Talc, and Purified Water. Apply this dispersion over the loaded and overcoated sugar spheres using a fluid bed coating machine.
- 20    5.    Overcoating      Prepare a second overcoating solution by dispersing Opadry White in Purified Water. Apply this dispersion over the non-release coated naltrexone spheres using a fluid bed coating machine
- 25    6.    Curing      Cure the spheres at 45°C for approximately 48 hours.